

Remarks

Claims 78, 81, 83, 85-87, and 89 have been amended. This application presently contains claims 78-90. No new matter is added by these amendments. Support for these amendments may be found in the original claims, the sequence listing, the figures, and throughout the specification, *e.g.*, at page 42, line 22 through page 43, line 24; page 45, lines 8-17; page 50, line 13 through page 51, line 2; page 52, lines 11-14; page 54, line 5 through page 74, line 5; page 69, lines 6-18; page page 83, line 14 through page 85, line 15; page 88, lines 14-24; in Table 2 and Tables 4-6. Applicants respectfully request entry of the foregoing amendments and submit that these amendments put the application in condition for immediate allowance or appeal.

A. Rejections under 35 U.S.C. § 112, second paragraph (Indefiniteness)

Rejections of Claim 78

Claim 78 stands rejected under 35 U.S.C. § 112, second paragraph. The Office alleges that “[a]t claim 78(A), it is unclear if the soybean plant bearing an rhg1 SCN resistant allele is homozygous at the locus and if the soybean plant bearing an rhg1 sensitive allele is homozygous for Rhg1, or if the soybean plant bearing the sensitive allele can be heterozygous and also resistant and essentially the same soybean plant bearing the resistant allele, only heterozygous.” Final Action at page 3. Applicants respectfully disagree. Nevertheless, in order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have amended claim 78. Applicants respectfully submit that the grounds for this alleged indefiniteness rejection of claim 78 are rendered moot. Applicants therefore respectfully request that this indefiniteness rejection be withdrawn.

Claim 78 also stands rejected as allegedly indefinite in the recitation of “allele is derived from.” Final Action at page 3. The Office alleges that “[t]here is no indication in the instant claim that the soybean bearing an rhg1 resistance allele is descended from the listed soybean lines, or how the derived allele is introduced into the soybean plant used in the method.” Final Action at page 3. Applicants respectfully disagree. However, in order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have amended claim 78.

Applicants respectfully submit that the grounds for this alleged indefiniteness rejection of claim 78 are rendered moot. Applicants therefore respectfully request that this indefiniteness rejection be withdrawn.

Claim 78 also stands rejected as indefinite because the sole designation of a plant by its breeding line name or number, or by a commercial variety designation is allegedly arbitrary and creates ambiguity in the claims. Final Action at pages 3-4. Applicants respectfully disagree. Applicants submit that plant breeding line names or commercial variety designations provide an unambiguous reference to individual plants. For example, soybean plants are listed according to plant breeding line name in the Germplasm Resources Information Network (GRIN) Database, which is maintained by the National Plant Germplasm System of the Agricultural Research Service, of the United States Department of Agriculture. *See, e.g.,* http://www.ars-grin.gov/cgi-bin/npgs/html/tax_site_acc.pl?SOY%20Glycine%20max. Applicants respectfully submit that a person of ordinary skill in the art would understand the metes and bounds of claim 78. Applicants respectfully submit that the grounds for this alleged indefiniteness rejection of claim 78 are overcome. Applicants therefore respectfully request that this indefiniteness rejection be withdrawn.

Rejection of Claims 80, 81, 82, 84, 86, and 89

Claims 80, 81, 82, 84, 86, and 89 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite in the recitation of “capable of detecting” and “markers.” Final Action at page 4. Applicants respectfully disagree.

The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied*, 112 S.Ct. 169 (1991). M.P.E.P. § 2173.02 states that “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.”

The instant specification recites “[i]n a preferred embodiment, the nucleic acid marker is capable of detecting an *rhg1* SNP or INDEL set forth in table 2.” Specification at page 83, lines 25-26. The specification further recites, “[i]n another preferred embodiment the nucleic acid marker is a nucleic acid molecule capable of acting as a PCR primer to amplify an *rhg1* or *Rgh4* coding region.” Specification at page 84, lines 1-3. In addition, the specification recites as follows:

As used herein, a “marker” is an indicator for the presence of at least one phenotype or polymorphism, such as single nucleotide polymorphisms (SNPs), cleavable amplified polymorphic sequences (CAPS), amplified fragment length polymorphisms (AFLPs), restriction fragment length polymorphisms (RFLPs), simple sequence repeats (SSRs), or random amplified polymorphic DNA (RAPDs). A “nucleic acid marker” as used herein means a nucleic acid molecule that is capable of being a marker for detecting a polymorphism or phenotype.

See, e.g., specification at page 83, lines 16-22. As such, Applicants submit that the specification adequately defines the metes and bounds of the claim terms “capable of detecting” and “markers.”

Applicants respectfully submit that one of ordinary skill in the art, reading the instant specification in light of their understanding of the art, would understand the meaning of the claim terms “capable of detecting” and “marker.” As such, Applicants request that the indefiniteness rejection of claims 73 and 75 be withdrawn.

Rejection of Claims 81, 83, 85, 87 and 89

The Office alleges that claims 81, 83, 85, 87 and 89 are indefinite due to “the use of arbitrary numbers to designate polymorphisms.” Final Action at page 4. Applicants respectfully disagree. Nevertheless, in order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have amended claims 81, 83, 85, 87 and 89. Applicants respectfully submit that the grounds for the alleged indefiniteness rejection of claims 81, 83, 85, 87 and 89 are rendered moot. Applicants therefore respectfully request that the indefiniteness rejection be withdrawn.

Rejection of Claim 86

Claim 86 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite in the recitation of “using ... marker assisted selection.” Final Action at page 4. Applicants respectfully disagree. However, in order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have amended claim 86. Applicants respectfully submit that the grounds for the alleged indefiniteness rejection of claim 86 are rendered moot. Applicants therefore respectfully request that the indefiniteness rejection be withdrawn.

Rejection of Claims 86 and 89

Claims 86 and 89 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite in the recitation of “introgressing.” Final Action at page 4. Applicants respectfully disagree.

The instant specification recites “[m]arker assisted introgression of traits into plants has been reported.” Specification at page 73, line 7. The specification also recites, “[m]arker assisted introgression involves the transfer of a chromosome region defined by one or more markers from one germplasm to a second germplasm. In a preferred embodiment the introgression is carried out by backcrossing with an *rhg1* or *Rhg4* resistant soybean recurrent parent.” Specification at page 73, lines 7-10. Applicants respectfully submit that the grounds for the alleged indefiniteness rejection of claims 86 and 89 are overcome. Applicants therefore respectfully request that the indefiniteness rejections be withdrawn.

B. Rejections under 35 U.S.C. § 112, first paragraph (Written Description)

Claims 78-85 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. The office alleges that “‘PI404198B’ and ‘PI43849B’ have not been described in the instant Application and did not appear in the claims as originally filed.” Final Action at page 5. Applicants respectfully disagree. *See, e.g.*, specification at page 51 (Table 4) and page 53 (Table 5). In order to facilitate prosecution, and

without acquiescing to the Examiner's arguments, Applicants have amended claim 78 to recite 'PI404198 B' and 'PI43849 B.'

For at least the foregoing reasons, Applicants submit that the written description rejections under 35 U.S.C. § 112, first paragraph, are overcome or rendered moot. Applicants therefore respectfully request that the written description rejections be withdrawn.

C. *Rejections under 35 U.S.C. § 112, first paragraph (Written Description)*

Claims 78-90 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. The Office alleges that "Applicant does not describe the genus of nucleic acid markers required to identify an rhg1 SCN resistant allele, or the specific polymorphisms as broadly claimed." Final Action at page 6. The Office alleges that "[a]s shown in Table 2 on pages 44-45 of the specification, the nucleotide bases described do not specifically identify an rhg1 SCN resistant allele because specific single nucleotide polymorphisms appear in both resistant and susceptible soybean varieties." Final Action at page 7. Applicants respectfully disagree.

An adequate written description of a genus of nucleic acids may be achieved by means of a "recitation of a representative number of [members], ...or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Moreover, the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...*i.e.*, complete or partial structure, other physical and or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). (quoting from Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001)).

Applicants disagree with the Office's assertion that the instant specification "does not specifically describe nucleic acid markers that can be used to identify an rhg1 SCN resistant allele." Final Action at page 7. Applicants submit that Table 1, in combination with the

sequence listing, describes a representative number of nucleic acid primer sequences that may be used to detect and analyze the polymorphisms set forth in Table 2. *See, e.g.*, Table 1, pages 25-30, listing SEQ ID NOs: 417, 418, 439, 440, 533, 534, 583, 584, 607, and 608; *see also* specification at page 17, lines 3-9 (indicating, *e.g.*, that SEQ ID NOs: 401-1096 correspond to primer sequences used in PCR to generate the amplicon sequences in Table 1). The specification also sets forth methods for using such nucleic acid primers to detect polymorphisms. *See, e.g.*, specification at page 60, line 8 through page 62, line 27; and Example 1.

Applicants also disagree with the Office's assertion that "[a]s shown in Table 2 on pages 44-45 of the specification, the nucleotide bases described do not specifically identify an rhg1 SCN resistant allele because specific single nucleotide polymorphisms appear in both resistant and susceptible soybean varieties." Final Action at page 7. Applicants submit that a person of ordinary skill in the art would understand that readily available methods can be used to establish that a particular polymorphism has a statistically significant correlation with an SCN resistant phenotype. Moreover, the specification describes examples of such statistical methods. *See, e.g.*, specification at page 62, line 15 through page 63, line 23; page 70, line 14-27; and page 108, lines 17-25.

Applicants respectfully submit that, in addition to the polymorphisms set forth in Table 2, the specification sets forth primers that may be used to detect these polymorphisms, as well as examples of statistical methods that may be used to establish a statistically significant correlation between the presence of a particular polymorphism and an SCN resistant phenotype. For at least these reasons, Applicants respectfully disagree with the Office's assertion that the specification "does not describe the genus of nucleic acid markers required to identify an rhg1 SCN resistant allele, or the specific polymorphisms as broadly claimed." Final Action at page 6.

Applicants disagree with the Office's allegation that claims 78-90 contain subject matter that was not adequately described in the specification. For at least the foregoing reasons, Applicants submit that the written description rejections under 35 U.S.C. § 112, first paragraph, have been overcome or rendered moot. Applicants therefore respectfully request that the written description rejections be withdrawn.

D. Rejections under 35 U.S.C. § 112, first paragraph (Enablement)

Claims 78-90 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Final Action at page 7. The Office alleges that “[t]able 2 on pages 44-45 of the specification teaches various single nucleotide polymorphisms of various soybean lines, but there does not seem to be a correlation between such polymorphisms and the presence of an *rhg1* SCN resistant allele.” Final Action at page 8. The Office further asserts that “[a]s the nucleic acid markers are crucial to practicing the claimed methods, it is Applicants’ burden to teach one of skill in the art at the time of the invention how to use the invention without undue trial and error experimentation, that being screening through a myriad of nucleic acid markers to identify those that can be used to identify an *rhg1* SCN resistant allele as broadly claimed.” Final Action at page 9. Applicants respectfully disagree.

As described above, in addition to the polymorphisms set forth in Table 2, the instant specification sets forth primers that may be used to detect these polymorphisms, as well as examples of statistical methods that may be used to establish a statistically significant correlation between the presence of a particular polymorphism and an SCN resistant phenotype. Although some routine experimentation may be required to confirm that the nucleic acid markers of Table 2 are statistically correlated with an SCN resistant phenotype, Applicants respectfully submit that such experimentation would not be undue. Applicants note that the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re. Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). Time and difficulty of experiments are not determinative if they are merely routine. M.P.E.P. § 2164.06, page 2100-186.

To the extent that the Office suggests there is a requirement for *a priori* predictability without recourse to any experimentation, that position is without legal support. *Cf. Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) (“[t]hat some experimentation is necessary does not preclude enablement”). The proper test of enablement in such a situation is whether the disclosure “adequately guide[s] the art

worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.” See *In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991).

The Final Action expresses concern that testing of the putative positives would entail screening through some false positives. Final Action at page 9. This concern is misplaced. “It is not a function of the claims to specifically exclude...possible inoperative substances.” *Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) (citing *In re Dinh-Nguyen*, 492 F.2d 856, 858-59, 181 U.S.P.Q. 46, 48 (C.C.P.A. 1974)). The case law does not require “each and every compound within a claim to be equally useful for each and every contemplated application.” *Ex Parte Cole*, 223 U.S.P.Q. 94, 95 (B.P.A.I. 1983).

There is no legal requirement that each and every polymorphism encompassed by the claims be useful for every contemplated utility. What is required is that the art worker know how to determine, after reasonable experimentation, whether a particular polymorphism is useful for a particular utility. The Final Action has not contended, nor can it contend that this is unachievable with the polymorphisms of the present claims. Instead, an improper test has been manufactured and applied which requires (without legal authority) demonstration of *a priori* knowledge of whether a particular polymorphism within the claimed genus would work.

Applicants respectfully disagree with the Office’s assertion that claims 78-90 contain subject matter that was not described in the specification in such as way as to enable one skilled in the art to make and/or use the invention without undue experimentation. Applicants therefore submit that the enablement rejections under 35 U.S.C. § 112, first paragraph, have been overcome or rendered moot. Applicants therefore respectfully request that the enablement rejections be withdrawn.

E. Rejections under 35 U.S.C. § 112, first paragraph (Enablement)

Claims 78-85 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Final Action at page 8. The Office alleges that the invention employs novel plants to practice the claimed invention. Final Action at page 9. Applicants respectfully disagree that the claimed invention employs novel plants. *See, e.g.*, Germplasm Resources Information Network (GRIN) Database, maintained by the National Plant Germplasm System of the Agricultural Research Service, of the United States Department of Agriculture, available at http://www.ars-grin.gov/cgi-bin/npgs/html/tax_site_acc.pl?SOY%20Glycine%20max. With respect to soybean lines ‘A2869’ and ‘AG4301,’ Applicants respectfully submit that Asgrow Seeds are now sold through the assignee of the instant application. *See, e.g.*, specification at page 69, lines 6-13, and attached printouts from the online seed catalog, http://www.monsanto.com/monsanto/us_ag/layout/seed/catalog/default.asp.

For at least these reasons, Applicants submit that the enablement rejection under 35 U.S.C. § 112, first paragraph, has been overcome or rendered moot. Applicants therefore respectfully request that the enablement rejection be withdrawn.

F. Rejections under 35 U.S.C. §102(e)

Claims 78 and 79 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by Lightfoot *et al.* (U.S. Patent 6,300,541 B1, filed 14 January 1997). Final Action at page 10. The Office alleges that “Lightfoot discloses a method of conveying soybean sudden death resistance into a non-resistant soybean germplasm comprising using marker SATT309 to identify a resistant soybean and introgressing said resistance into a non-resistant soybean germplasm (claim 4).” Final Action at page 10. The Office further alleges that “Lightfoot discloses that said source of resistance can be from a descendant of Jack (the commercial name for soybean line PI540556),” and that Lightfoot therefore teaches all of the required steps of the claimed invention. Final Action at pages 10-11. Applicants respectfully disagree.

In order to facilitate prosecution, and without acquiescing to the Examiner's arguments, Applicants have amended claim 78 to read on, in part, said at least one SCN resistant soybean plant bearing said rhg1 SCN resistant allele is selected from the group consisting of PI200499, A2869, PI404198 B, PI404166, PI548988, PI507354, PI438489 B, PI84751, PI407922, AG4301, and SCN resistant progeny thereof.


In order for a reference to anticipate a claimed invention, it must teach exactly what is claimed. *Titanium Metals Corp. v. Banner* 778 F.2d 775, 227 U.S.P.Q.2d 1766 (Fed. Cir. 1987), *cert. denied* 484 U.S. 1007 (1988). Whatever else Lightfoot *et al.* describes, it does not describe one or more soybean lines selected from the group consisting of PI200499, A2869, PI404198 B, PI404166, PI548988, PI507354, PI438489 B, PI84751, PI407922, and AG4301. Moreover, Applicants submit that the rejection is obviated by the amendment removing the PI540556 line from the Markush group. In view of the preceding, Applicants submit that Lightfoot *et al.* does not anticipate amended claims 78-79.

In view of the foregoing, Applicants respectfully submit that the grounds for this anticipation rejection has been overcome or rendered moot, and request withdrawal of the rejection of claims 78 and 79 under 35 U.S.C. §102(e).

Conclusion

In view of the above, each of the presently pending claims is believed to be in condition for immediate allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is respectfully requested to contact Applicants' undersigned representative at 202.942.5512 to address any unresolved issues remaining in this application.

Respectfully submitted,



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